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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO.       |
|--|-------------|----------------------|-------------------------------|------------------------|
| 10/522,879   | 09/30/2005  | Lyubov Ryabova       | 58763.000029                  | 5249                   |
| 21967 7590 05/02/2007<br>HUNTON & WILLIAMS LLP<br>INTELLECTUAL PROPERTY DEPARTMENT<br>1900 K STREET, N.W.<br>SUITE 1200<br>WASHINGTON, DC 20006-1109 |             |                      | EXAMINER<br>PROUTY, REBECCA E |                        |
|  |             |                      | ART UNIT<br>1652              | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>05/02/2007       | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/522,879 | <b>Applicant(s)</b><br>RYABOVA ET AL. |  |
|                              | <b>Examiner</b><br>Rebecca E. Prouty | <b>Art Unit</b><br>1652               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

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Claims 15-20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 9-14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference in these claims is the use of the term "cell-free system" in claims 9-14 and "cell-free extract" in claims 15-20. It is unclear however these two phrases differ and thus the claims appear to be duplicates.

Claim 22 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 7, 12, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague in the recitation of "adapting ATP sulfurylase concentration according to the experimental

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conditions and the biological macromolecules to be synthesized" as it is unclear what acts this encompasses. For further examination this is assumed to be synonymous with adjusting the ATP sulfurylase concentration to optimize the amount of protein synthesized.

Claims 12 and 18 are indefinite in the recitation of "derived from" as it is unclear if this is synonymous with "isolated from" or if it includes other things. Furthermore it is unclear how a protein is "derived from" a vector as vectors do not comprise proteins.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Blakesley et al. (WO 98/22615) in view of Swartz et al. (WO 00/55353).

Blakesley et al. teach methods for preventing inhibiting nucleic acid synthesis comprising adding ATP-sulfurylase and its substrate (adenosine 5'-phosphosulfate) to a cell-free nucleic acid synthesis system (page 11). Blakesley et al. teach that the enzyme can be isolated from natural sources or produced recombinantly (page 20) and can be added at the beginning of the reaction or supplemented in addition throughout (page 19). Blakesley et al. teach that concentration of ATP-sulfurylase may range from about 1 U/ml to about 2000 U/ml, preferably about 2 U/ml (page 19). Blakesley et al. teach that the disclosed methods be used in methods where improvement of synthesis of nucleic acids by a polymerase is desired and where pyrophosphorolysis is deemed counter-productive. Blakesley et al. do not specifically teach the use of the disclosed methods with *in vitro* transcription/translation systems.

Swartz et al. teach *in vitro* transcription/translation systems having a variety of systems for generating the necessary ATP for nucleic acid and protein synthesis. Swartz et al. teach that high concentrations of inorganic phosphate are inhibitory of such ITT systems (page 11).

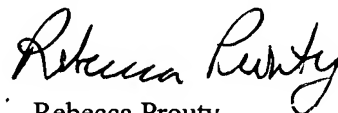
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As the ITT systems of Swartz et al. clearly require nucleic acid synthesis, it would have been obvious to one of ordinary skill in the art to employ the method of enhancing nucleic acid synthesis described by Blakesley et al. as Blakesley et al. clearly suggest that the disclosed methods would be useful for any system in which improvement of synthesis of nucleic acids by a polymerase is desired.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Prouty  
Primary Examiner  
Art Unit 1652